K 123493

DEC 1 3 2012

Special 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date 510K summary prepared: November 8th, 2012

Submitter's Name, address, telephone number, a contact person:

Submitter's Name :	Vatech Co., Ltd.
Submitter's Address:	23-4, Seogu-Dong, Hwaseong-Si, Gyeonggi-Do, 445-170, Korea Republic
Submitter's Telephone:	Tel: +82-31-379-9585 Fax: +82-31-379-9638
Contact person:	Mr. Mr. Sung-Hee Park
Official Correspondent: **(U.S. Designated agent)**	Dave Kim (davekim@mtech-inc.net)
Address:	12946 Kimberley Ln, Houston, TX 77079
Telephone:	+713-467-2607
Fax:	+713-464-8880

Name of the device, including the trade or proprietary name if applicable, the common or usual name and the classification name, if known:

Trade/proprietary name:	VEX-S100W
Common Name:	Dental Extraoral Source X-ray System
Classification Name :	Unit, X-ray, Extraoral With Timer (21CFR 872.1800, Product code EHD, class2)

Product Code: EHD

Predicate Device :

Manufacturer : Vatech Co.,Ltd.
Device : ESX
510(k) Number : K092103 (Decision Date – 10/09/2009)

Device Description :

VEX-S100W is an extraoral source dental X-ray system intended for intraoral imaging. It consists of X-ray generator, X-ray controller, beam limiting device, operation panel and mechanical arm. The X-ray controller allows for accurate exposure control, and an adjustable mechanical arm allows for easy positioning. The system can be used either with conventional film or a digital imaging system.

Indication for use :

The VEX-S100W is an extraoral source of X-rays, intended to be used for producing diagnostic dental radiographs for treatment of disease of the teeth, jaw and oral structures.

Summary of the technological characteristics of the device compared to the predicate device:

VEX-S100W is described in this special 510(k) submission has the same indications for use and similar technical characteristics as ESX (K092103) of Vatech Co., Ltd.

Characteristic	Proposed Vatech Co., Ltd. VEX-S100W	Predicate Vatech Co., Ltd. ESX
510(k) number	-	K092103, dated on 10/09/2009
Indications for use	The VEX-S100W is an extraoral source of X-rays, intended to be used for producing diagnostic dental radiographs for treatment	The ESX is an extraoral source of X-rays, intended to be used for producing diagnostic dental radiographs

<table>
<tr><td></td><td>of disease of the teeth, jaw and oral structures.</td><td>for treatment of disease of the teeth, jaw and oral structures.</td></tr>
<tr><td>Performance Specification</td><td>Intraoral X-ray equipment</td><td>Intraoral X-ray equipment</td></tr>
<tr><td>Input Voltage</td><td>AC 100-120 / 200-240 V</td><td>AC 100/230 V</td></tr>
<tr><td>Tube Voltage</td><td>50-70 kVp (Refer to the table)
<table>
<tr><td>Tube Voltage (kVp)</td><td>Tube Current (mA)</td><td>Exposure time (s)</td></tr>
<tr><td>50</td><td>4~7</td><td>0.04~2</td></tr>
<tr><td>51~ 59</td><td>4~6</td><td>0.04~2</td></tr>
<tr><td>60</td><td>4~7</td><td>0.04~0.5</td></tr>
<tr><td>61 ~ 69</td><td>4~5</td><td>0.04~2</td></tr>
<tr><td>70</td><td>4~6</td><td>0.04~0.5</td></tr>
<tr><td colspan="3">*Voltage : step 1 kVp
*Current : step 1 mA
*Time : step 0.01 s</td></tr>
</table></td><td>65 kVp</td></tr>
<tr><td>Tube Current</td><td>4-7 mA (Refer to the table)
<table>
<tr><td>Tube Voltage (kVp)</td><td>Tube Current (mA)</td><td>Exposure time (s)</td></tr>
<tr><td>50</td><td>4~7</td><td>0.04~2</td></tr>
<tr><td>51~ 59</td><td>4~6</td><td>0.04~2</td></tr>
<tr><td>60</td><td>4~7</td><td>0.04~0.5</td></tr>
<tr><td>61 ~ 69</td><td>4~5</td><td>0.04~2</td></tr>
<tr><td>70</td><td>4~6</td><td>0.04~0.5</td></tr>
<tr><td colspan="3">*Voltage : step 1 kVp
*Current : step 1 mA
*Time : step 0.01 s</td></tr>
</table></td><td>5 mA</td></tr>
<tr><td>Exposure Time</td><td>0.04 – 2.0 s (Refer to the table)
<table>
<tr><td>Tube Voltage (kVp)</td><td>Tube Current (mA)</td><td>Exposure time (s)</td></tr>
<tr><td>50</td><td>4~7</td><td>0.04~2</td></tr>
<tr><td>51~ 59</td><td>4~6</td><td>0.04~2</td></tr>
<tr><td>60</td><td>4~7</td><td>0.04~0.5</td></tr>
<tr><td>61 ~ 69</td><td>4~5</td><td>0.04~2</td></tr>
<tr><td>70</td><td>4~6</td><td>0.04~0.5</td></tr>
<tr><td colspan="3">*Voltage : step 1 kVp
*Current : step 1 mA
*Time : step 0.01 s</td></tr>
</table></td><td>0.05 – 1.5 s</td></tr>
</table>

Total Filtration	> 2.0 mm Al	> 2.0 mm Al
Focal Spot Size	0.4 mm	0.8 mm
Focal length (SSD)	1) Round: 200 mm (Default) 2) Round: 300 mm (Option) 3) Rectangular Cone: 200 mm (Option) 4) Rectangular Cone: 300 mm (Option)	7.9 in
Anode material	Tungsten	Tungsten
Compatible with film and digital imaging	Yes	Yes
Weight (kg)	18.5 kg (40.8 lbs)	23.8 kg (52.5 lbs)

Note: The weight of the proposed device is less than the predicate device. The new X-ray tube head of the proposed device is more compact in design with the focal spot size of 0.4 mm compared to 0.8 mm of the predicate device. The mechanical arm of VEX-S100W is lighter than the predicate device and moves more smoothly compared to the predicate device with the improved arm joint function for better user experience and convenience.

The proposed device and predicate device are substantially equivalent, having the same intended use, form factor, material, performance and safety characteristics. The operating range of the X-ray tube, including tube voltage, tube current, exposure time, focal length and X-ray filtration of the proposed and predicate devices are similar. The product code for both proposed device and predicate device is categorized as EHD; equivalence between these models is evident. The differences are cosmetic and component use only. These differences do not raise any new questions of safety or effectiveness.

Summary of Performance Testing:

The performance test has been conducted for VEX-S100W to verify compliance of the installation with specifications affecting the image quality and patient dose and to detect malfunctions that are not in agreement with those specifications. All test instruments are calibrated calibration lap providing traceability to international standards (ISO/IEC 17025) The calibration is performed by comparison with measuring and test equipment, which is verified via factory measurement standards according to DIN EN ISO 9001/9003. Imaging. Imaging Performance Test is based on IEC61223-3-4 and partly referred to IEC60601-1, IEC60601-1-1, IEC60601-1-3, IEC60601-2-7, IEC60601-2-28, IEC60601-2-32 standard. All tests were satisfactory. Moreover, the performance and safety characteristics between VEX-S100W and ESX are very similar in terms of the indications for use, material and form factor. The primary difference is the focal spot size. The focal spot, the area on the target of the x-ray tube which the electron stream strikes and from which x-rays are emitted, is smaller for the new VEX-S100W compared to the predicate device. The smaller the area of the focal spot, the better is the diagnostic detail in the x-ray image.

This premarket notification submission for a determination of substantial equivalence does not require nor rely on the clinical testing.

Safety, EMC and Performance Data:

Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1(A1+A2, 1995), IEC 60601-1-1 (2001), IEC 60601-1-3 (Ed. 1, 1994), IEC 60601-2-7 (1998), IEC 60601-2-28 (Ed. 1, 1993) and IEC 60601-2-32 (Ed. 1, 1994) were performed, and EMC testing were conducted in accordance with standard IEC 60601-1-2.

Acceptance test according to IEC 61223-3-4 was performed.
All test results were satisfactory.

Conclusion:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification. Vatech Co., Ltd. concludes that VEX-S100W is safe and effective and substantially equivalent to predicate device as described herein.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 13, 2012

Vatech Co., Ltd.
C/O Mr. Sung-Hee Park
Manager
23-4, Seogu-Dong
Hwaseong-si, Gyeonggi-Do, 445-170
Republic of Korea

Re: K123493
Trade/Device Name: VEX-S100W
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: EHD
Dated: November 9, 2012
Received: November 15, 2012

Dear Mr. Park:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris -S

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123493

Device Name: VEX-S100W

Indications for Use:

The VEX-S100W is an extraoral source of X-rays, intended to be used for producing diagnostic dental radiographs for treatment of disease of the teeth, jaw and oral structures.

Prescription Use __Yes___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Janine M. Morris -S
2012.12.13 13:00:41 -05'00'

(Division Sign Off)

Division of Radiological Health

Office of *In Vitro* Diagnostic and Radiological Health

510(k)_____